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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/768,953

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Amedeo Leonardi

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EXAMINER

ROYDS, LESLIE A

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

06/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/768,953

Applicant(s)

LEONARDI ET AL.

Examiner

Leslie A. Royds

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,21-27,31-40 and 43-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,11-20,28-30,41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-58 are presented for examination.

Applicant's Amendment filed April 2, 2007 has been received and entered into the present application.

Claims 1-58 are pending and claims 9-10, 21-27, 31-40 and 43-58 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 1-8, 11-20, 28-30 and 41-42 are under examination and claims 1 and 3-6 are amended.

Applicant's arguments, filed April 2, 2007, have been fully considered but they are not deemed to be persuasive. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-8, 11-20, 28-30 and 41-42 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cosford et al. (WO 01/16121; 2001) in view of Bonney et al. ("Bladder Dysfunction in Schizophrenia", *Schizophrenia Research*, 25(1997):243-249) and Nilvebrandt ("Clinical Experiences with Tolterodine", *Life Sciences*, 68(2001):2549-2556), each already of record, for the reasons of record set forth at pages 5-9 of the previous Office Action dated January 24, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the present rejection, stating that there is no motivation to combine Cosford et al. with Bonney et al. Applicant submits that Bonney teaches urinary incontinence as being associated with schizophrenia, but fails to suggest the use of agents for treating schizophrenia for the treatment of urinary incontinence. Applicant further relies upon the fact that psychiatric medications used to treat schizophrenia may contribute to incontinence and alleges that Bonney et al. does not consider agents useful for treating schizophrenia to also be useful for treating lower urinary tract disease. Applicant additionally asserts Nilvebrandt fails to remedy the deficiencies of Cosford et al. or Bonney et al.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, it is noted that Bonney et al. clearly teaches the association of urinary incontinence in patients suffering from schizophrenia. Please see Bonney et al., page 246, Table 2. Such a teaching clearly raises the reasonable expectation that the schizophrenic patient of Cosford et al. would be concomitantly experiencing urinary incontinence, absent any factual evidence to the contrary.

Furthermore, Bonney et al. also clearly teaches the neurobiological and pathophysiological similarities between schizophrenia and urinary incontinence, such that the ventricular enlargement, neuronal loss with gliosis and dopamine dysregulation that occurs with schizophrenia subsequently interrupts the pathway of bladder control and, thus, results in urinary incontinence. In other words, urinary incontinence in schizophrenia patients occurs independently (i.e., not necessarily related to)

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urinary symptoms that may coincidentally result from treatment with conventional schizophrenia therapies.

Accordingly, the fact that Cosford et al. teaches the claimed MTEP compound for the treatment of patients suffering from schizophrenia and Bonney et al. teaches the clear association of the occurrence of concomitant urinary incontinence in schizophrenia patients as a result of the physiological brain abnormalities that result from such a psychiatric condition raises the reasonable expectation that the MTEP compound would be administered to a patient suffering from urinary incontinence associated with schizophrenia. This clearly meets the claimed limitations directed to the administration of MTEP to a patient suffering from urinary incontinence. Though the prior art may not have previously recognized the urinary incontinence-ameliorating effect of the claimed MTEP compound, a compound and its properties are inseparable such that any effect that MTEP may have in treating urinary incontinence would have necessarily been present, absent factual evidence to the contrary. In other words, if the same compound is administered to a subject suffering from, or with a strong likelihood of suffering from, the same condition as claimed (i.e., urinary incontinence), regardless of whether the incontinence is the primary condition being treated or not, then whatever effect such a compound has in treating urinary incontinence must necessarily be present. Products of identical composition cannot have mutually exclusive properties when administered under the same circumstances or, in the present case, the same host. Please see MPEP §2112.

Though Applicant argues that psychiatric medications contribute to incontinence, such an allegation is a generalized statement that Applicant has extrapolated to a specific species of medication without providing any reasoning or evidence to support such a conclusion as to why one of ordinary skill in the art at the time of the invention would have been led away from using MTEP in a patient because of an expectation of inducing urinary incontinence, not treating urinary incontinence. Generic allegations that “psychiatric medications” as a general class contribute to urinary incontinence fails to establish any

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correlation between a specific species of drug (i.e., MTEP) and the induction of urinary incontinence in a patient. In addition, Applicant's conclusory statement that one of skill in the art would not have been imbued with a reasonable expectation of success in using the MTEP compound for the treatment of urinary incontinence because psychiatric medications are known to contribute to incontinence fails to appreciate that, though incontinence and schizophrenia are two separate conditions, it remains that the two conditions occur simultaneously with reasonable predictability and are, therefore, logically not separable from one another. As a result, it remains that the cited prior art renders Applicant's claimed invention to the treatment of urinary incontinence using the compound MTEP *prima facie* obvious because the prior art recognizes the therapeutic application of treating patients with schizophrenia, and a reasonable predictability of concomitant urinary incontinence occurring with the schizophrenia, with the claimed MTEP compound. Though mechanisms of action or new properties of a compound are no doubt important contributions to scientific and pharmaceutical development, the assessment of patentability under 35 U.S.C. 102 and/or 35 U.S.C. 103 is based upon the therapeutic applications and effects of the compounds, not the mechanisms and/or properties by which they exert such a therapeutic effect.

Lastly, regarding Applicant's argument that Nilvebrandt fails to remedy the deficiencies of Cosford et al. and Bonney et al., Applicant is reminded that the rejections made under 35 U.S.C. 103(a) are based upon the combination of references. Applicant clearly does not address the combined teachings as a whole, but rather focuses solely on the discrete teachings of each of the cited references and asserts that, since neither reference teaches the presently claimed invention in its entirety, that the rejection is improper. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the combination of the cited references. Please reference *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re*

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Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Moreover, rejections under 35 U.S.C. 103(a) are based upon combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one of ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. Please see also *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In view of such, arguments regarding the discrete teachings of each of the secondary references without considering the combination as a whole are not persuasive and will not be further considered herein.

For these reasons, and those previously made of record at pages 5-9 of the Office Action dated January 24, 2007, rejection of claims 1-8, 11-20, 28-30 and 41-42 remains proper and is **maintained**.

Conclusion

Rejection of claims 1-8, 11-20, 28-30 and 41-42 remains proper and is **maintained**.

Claims 9-10, 21-27, 31-40 and 43-58 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-**

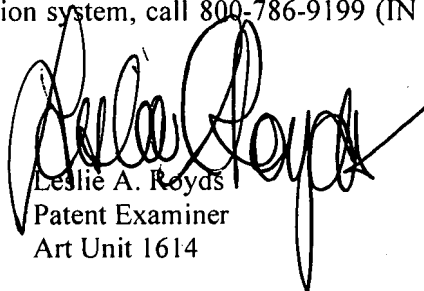
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MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie A. Royds
Patent Examiner
Art Unit 1614

June 6, 2007



ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER